REMARKS

The specification

As noted by the Examiner, the present application claims priority to U.S. Serial Nos. 09/052,521, 08/842,842 and 08/880,855. The specification has been amended to include the priority data.

The Claims

Pursuant to the restriction requirement set forth in paper no. 3, Applicants have elected Group XI, Claim 42. Accordingly, Claims 1-41 have been cancelled without prejudice or disclaimer as being directed to a non-elected invention.

Claim 42 has been cancelled without prejudice or disclaimer and Claims 43-54 have been added. The new claims are fully supported in the specification: for example, Claims 43 and 44 are disclosed at p. 25, line 32 to p. 26, line 2; p. 28, line 35 to p. 29, line 3 and Example 8. The new claims do not introduce new matter or raise new issues requiring further consideration and/or search. Entry of the new claims is respectfully requested.

Disclosure of Nucleotide and/or Amino Acid Sequences

The Examiner has indicated that the sequence listing does not comply with the requirements of 37 CFR 1.821 to 1.825 for the disclosure of nucleotide and/or amino acid sequences. Applicant submits herewith a substitute paper copy of the sequence listing and computer readable form thereof. It is believed that the application is in compliance with the requirements of 37 CFR 1.821 to 1.825.

Abstract of the disclosure

The Examiner has required that Applicant amend the abstract of the disclosure to include the method of Claim 42. Upon an indication of allowable subject matter, Applicant will amend the abstract to conform with allowed subject matter.

Rejection under 35 U.S.C. 112

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly contains subject matter which was not described in such a way as to reasonably convey that the inventor had possession of

Applicant respectfully disagrees.

Claim 42 is directed to a method of assessing the ability of a test compound to increase or decrease binding of OPGbp to ODAR. Detection of OPGbp binding to ODAR is taught in Example 13 of the

specification at p. 63. Additional methods for measuring the binding of OPGbp to ODAR in the absence and presence of test compounds are also taught at p. 26, line 9 to p. 29 line 17. One skilled in the art would recognize that the methods for measuring binding to OPGbp to ODAR could be applied to various OPGbp and ODAR polypeptides. It is clear that the specification describes the steps set forth in the method of Claim 42 and that Applicant had possession of the invention.

In alleging lack of written description, the Examiner has cited *Regents of the University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997). The decision in *Lilly* focused on adequate written description of claims directed to cDNA encoding vertebrate insulin and mammalian insulin where the specification disclosed rat insulin-encoding cDNA. *Lilly* was concerned with the written description of an invention involving a chemical genus (in this instance, a genus of DNA sequences encoding insulin) whereas the presently claimed subject matter deals with steps in a method for assessing an increase or a decrease in binding of OPGbp to ODAR. Applicant maintains that Claim 42 is distinct and different from the subject matter at issue in *Lilly* in that Claim 42 is not directed to OPGbp and ODAR sequences *per se* but to their use in a method. Applicant maintains that the decision in *Lilly* has not been properly applied.

Applicant points out that the structure of both murine and human OPGbp (Figures 1 and 4, respectively) and murine ODAR (Figure 10) were disclosed in the specification, as well as the structure of various biolgically active fragments. Human ODAR was known in the art (Anderson et al. Nature 390, 175-179 (1997) cited at p. 61, line 6 of the specification). The disclosure of OPGbp and ODAR nucleic acid sequences in the present application is more extensive than that for insuin cDNA in *Lilly*.

Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. 103

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 6,242,213) in view of Dougall (U.S. Patent Application Publication No. 2003/0021785).

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 6,017,729) in view of Dougall (U.S. Patent Application Publication No. 2003/0021785).

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (Nature, *supra*) in view of Dougall (U.S. Patent Application Publication No. 2003/0021785) and Ni et al. (U.S. Patent No. 5,981,220).

The Examiner argues that the screening method of Claim 42 would have been obvious in view of

Applicant further notes that the Dougall published U.S. application has a filing date of June 6, 2001 and therefore cannot be cited as prior art in the present case which claims priority to U.S. Serial No. 08/842,842, filed April 16, 1997.

Priority date for Claim 42

The Examiner argues that the subject matter of Claim 42 is not disclosed in parent applications 08/842,842 and 08/880,855 and is therefore entitled to the priority date of the parent application, 09/052,521. Applicant disagrees. Methods for identifying compounds which bind to OPGbp, where such compounds could increase or decrease OPGbp binding activity (i.e., agonists and antagonists of OPGbp), were taught in the earliest filed application, U.S. Serial No. 08/842,842, at p. 17, line 32 to p. 18, line 9. Such methods are clearly encompassed by the present claims. Applicant maintains that Claims 43-54 are entitled to the priority date of U.S. Serial No. 08/842,842.

CONCLUSION

Claims 43-54 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,

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